

Food and Drug Administration, HHS

§876.4730

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25049, June 12, 1989]

§876.4560 Ribdam.

(a) *Identification*. A ribdam is a device that consists of a broad strip of latex with supporting ribs used to drain surgical wounds where copious urine drainage is expected.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25049, June 12, 1989]

§876.4590 Interlocking urethral sound.

(a) *Identification*. An interlocking urethral sound is a device that consists of two metal sounds (elongated instruments for exploring or sounding body cavities) with interlocking ends, such as with male and female threads or a rounded point and mating socket, used in the repair of a ruptured urethra. The device may include a protective cap to fit over the metal threads.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996]

§876.4620 Ureteral stent.

(a) *Identification*. A ureteral stent is a tube-like implanted device that is inserted into the ureter to provide ureteral rigidity and allow the passage of urine. The device may have finger-like protrusions or hooked ends to keep the tube in place. It is used in the treatment of ureteral injuries and ureteral obstruction.

(b) *Classification*. Class II (performance standards).

§876.4650 Water jet renal stone dislodger system.

(a) *Identification*. A water jet renal stone dislodger system is a device used to dislodge stones from renal calyces (recesses of the pelvis of the kidney) by

means of a pressurized stream of water through a conduit. The device is used in the surgical removal of kidney stones.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998]

§876.4680 Ureteral stone dislodger.

(a) *Identification*. A ureteral stone dislodger is a device that consists of a bougie or a catheter with an expandable wire basket near the tip, a special flexible tip, or other special construction. It is inserted through a cystoscope and used to entrap and remove stones from the ureter. This generic type of device includes the metal basket and the flexible ureteral stone dislodger.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998]

§876.4730 Manual gastroenterology-urology surgical instrument and accessories.

(a) *Identification*. A manual gastroenterology-urology surgical instrument and accessories is a device designed to be used for gastroenterological and urological surgical procedures. The device may be nonpowered, hand-held, or hand-manipulated. Manual gastroenterology-urology surgical instruments include the biopsy forceps cover, biopsy tray without biopsy instruments, line clamp, nonpowered rectal probe, nonelectrical clamp, colostomy spur-crushers, locking device for intestinal clamp, needle holder, gastro-urology hook, gastro-urology probe and director, nonself-retaining retractor, laparotomy rings, nonelectrical snare, rectal specula, bladder neck spreader, self-retaining retractor, and scoop.